NOV 2 3 2004

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The Trabecular Metal Glenoid
Bigliani/Flatow® (B/F) The Complete Shoulder Solution

Submitter Name And Address:	Zimmer Trabecular Metal Technology, Inc. 80 Commerce Drive Allendale, New Jersey 07401-1600
Contact Person:	Marci Halevi
Phone Number:	(201) 818-1800 X 507
Fax Number:	(973) 829-0825
Date Prepared:	November 2, 2004
Device Trade Name:	The Trabecular Metal Glenoid, the B/F Complete Shoulder Solution
Device Common Name:	Glenoid Component
Classification Number and Name:	21 CFR 888.3660 & 888.3650; Prosthesis, shoulder, semi & non-constrained, metal/polymer cemented.

Substantial Equivalence:

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without premarket approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

Device Description:

The device is a monoblock glenoid component comprised of a Trabecular Metal base with an articular surface comprised of direct compression molded polyethylene. The TM Glenoid is designed to interface & articulate with Zimmer B/F humeral components and is available in one thickness option of 5 mm, and the same outer geometry and dimensions as the B/F glenoids cleared in K022377 and K031449.

510(k) Summary (Continued)

Indications for use: Prosthetic replacement with this device may be indicated for the treatment of severe pain or significant disability in degenerative, rheumatoid, or traumatic disease of the glenohumeral joint; un-united humeral head fractures of long duration; irreducible 3- and 4-part proximal humeral fractures; avascular necrosis of the humeral head; or other difficult clinical management problems where arthrodesis or resectional arthroplasty is not acceptable. The assembled humeral component may be used alone for hemiarthroplasty or combined with the glenoid component for total shoulder arthroplasty. Humeral heads with heights greater than 27 mm may be used for difficult clinical management problems involving rotator cuff deficiency where arthrodesis or conventional non-constrained arthroplasty is not acceptable. The Trabecular Metal Glenoid must be fully or partially cemented in place in the USA.

Device Technological Characteristics & Comparison to Predicate Device: The subject device possesses the same external geometry and dimensions, the same articulation geometry, the same minimum polyethylene thickness, and same size options as the predicate devices. The Trabecular Metal, direct compression molded polyethylene and monoblock design is similar to numerous cleared Zimmer Trabecular Metal devices. This 510(k) clearance provides a change in manufacturing technique to increase the interfacial area between the UHMWPE and the Trabecular Metal glenoid base.

Performance Data: An engineering analysis showed that the increased area of polyethylene infiltration does not adversely affect device strength and increases the area of attachment between the UHMWPE and the Trabecular Metal glenoid base.

Conclusion: The Trabecular Metal Glenoid is substantially equivalent to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 23 2004

Ms. Marci Halevi
Manager of Regulatory Affairs
Zimmer Trabecular Metal Technology
80 Commerce Drive
Allendale, New Jersey 07401-1600

Re: K043061
Trade/Device Name: Trabecular Metal Glenoid – B/F Complete Shoulder Solution
Regulation Numbers: 21 CFR 888.3660, 21 CFR 888.3650
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis, shoulder joint metal/polymer non-constrained cemented prosthesis
Regulatory Class: II
Product Codes: KWS, KWT
Dated: November 3, 2004
Received: November 4, 2004

Dear Ms. Halevi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K043061

Device Name: The Trabecular Metal Glenoid – The B/F Complete Shoulder Solution

Indications For Use:

Prosthetic replacement with this device may be indicated for the treatment of severe pain or significant disability in degenerative, rheumatoid, or traumatic disease of the glenohumeral joint; un-united humeral head fractures of long duration; irreducible 3- and 4-part proximal humeral fractures; avascular necrosis of the humeral head; or other difficult clinical management problems where arthrodesis or resectional arthroplasty is not acceptable. The assembled humeral component may be used alone for hemiarthroplasty or combined with the glenoid component for total shoulder arthroplasty. Humeral heads with heights greater than 27 mm may be used for difficult clinical management problems involving rotator cuff deficiency where arthrodesis or conventional non-constrained arthroplasty is not acceptable. The Trabecular Metal Glenoid must be fully or partially cemented in place in the USA.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

for **(Division Sign-Off)**
Division of General, Restorative, and Neurological Devices

Prescription Use (Per 21 CFR 801.109) X OR... Over-The-Counter Use

510(k) Number K043061

(Optional Format 1-2-96)